

REMARKS

This responds to the Office Action dated February 15, 2005. Claims 1-25 are pending in this application.

§103 Rejection of the Claims

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chekanov (U.S. Patent No. 6,201,991) and in view of Hauck (U.S. Patent No. 6,560,489). Applicant respectfully traverses the rejection because Hauck teaches away from the present invention and because proper motivation is lacking to combine Chekanov with Hauck.

The prior art must be considered in its entirety, including disclosures that teach away from the invention. *M.P.E.P.* § 2141.02. Hauck refers to a device to increase collagen type I production (col. 3 lines 42-45, col. 6 lines 57-62). Type I collagen has been shown to constitute a major part of total plaque protein, and thus plays an important role in plaque growth and arterial lumen narrowing. Claim 1 recites, among other things, ..., in the coronary artery to prevent plaque build-up in the coronary artery. Thus, Hauck and combinations of references that include Hauck teach away from the present invention.

The Office Action fails to establish proper *prima facie* obviousness because the proposed combination of documents does not teach or suggest the desirability of that combination. The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *M.P.E.P.* § 2143.01. Applicant respectfully submits that proper motivation is lacking to combine Chekanov with Hauck for several reasons.

Chekanov refers to a device to prevent or decrease size of the plaque in blood vessels (Abstract). Because Hauck refers to a device to increase collagen type I production (col. 3 lines 42-45, col. 6 lines 57-62), and because type I collagen has been shown to constitute a major part of total plaque protein, Hauck teaches away from the Chekanov device.

Additionally, Hauck refers to regulating the output of the current generator to maintain the field strength below the heart's depolarization threshold (col. 4 lines 23-25, lines 45-47, col. 5 lines 28-29), and refers to a risk of inducing a depolarization of the cardiac tissue resulting in an unwanted cardiac contraction (col. 3 approx. lines 48-50). Chekanov refers to a device to

cause or stimulate muscle contraction (*see* Chekanov col. 2 lines 61-62, col. 3 lines 42 - 49), and refers to a cardiomyostimulator (stimulating the myocardium) as an example of a pulse generator for its device (col. 2 lines 28-30). Chekanov apparently refers to avoiding muscle contraction only in reference to placing the device outside of skeletal muscle (col. 2 lines 39-44). Because Hauck teaches away from applying a stimulus to cause a contraction (i.e., a sub-threshold stimulus) while the Chekanov device apparently causes a contraction when placed in contact with muscle tissue, Hauck teaches away from the Chekanov device.

Further, Hauck refers to a device to promote angiogenesis (promotion of new blood vessels) (col. 3 lines 42-45, col. 6 lines 57-62) and refers to angiogenesis as an alternative method from re-opening clogged blood vessels in re-establishing blood flow to ischemic zones (col. 2 lines 52-62). Chekanov refers to a device to prevent or decrease size of the plaque in blood vessels (Abstract). Thus, Hauck teaches away from the Chekanov device.

Therefore, at least for the reasons that Chekanov refers to a device to prevent or decrease size of the plaque in blood vessels while Hauck refers to a device to increase collagen type I production, that Chekanov refers to a device to cause or stimulate muscle contraction while Hauck refers to regulating the output of the current generator to maintain the field strength below the heart's depolarization threshold, and that Chekanov refers to a device to prevent or decrease size of the plaque in blood vessels while Hauck refers to an alternative method of re-establishing blood flow to ischemic zones, Applicant submits that proper motivation is lacking within the documents to combine Hauck and Chekanov.

Furthermore, the proposed modification can not render references unsatisfactory for their intended purpose. *MPEP* § 2143.01. Because the Hauck device would increase collagen type I production while the Chekanov device is to prevent or decrease size of the plaque in blood vessels the proposed combination of Chekanov with Hauck would render the device in Chekanov device unsatisfactory for this purpose. Also, because Hauck refers to preventing the level of current from inducing unwanted heart depolarizations (Abstract) while Chekanov refers to using its device to stimulate muscle contractions (col. 1, lines 46-51), the proposed combination of Chekanov with Hauck would render the device in Hauck unsatisfactory for this purpose.

In addition, to establish proper *prima facie* obviousness, the references must teach or suggest all claim elements. Applicant is unable to find disclosure of all claim elements of all contested claims in the proposed combination of Chekanov and Hauck.

Regarding claim 6, 17:

Applicant is unable to find in the applied documents, generating the electric field includes periodically producing the electric field and spacing the electrical fields about (or less than) 10 seconds apart, among other things, in claims 6 and 17. Hauck teaches that sinusoidal frequencies of 2-200Hz although higher frequencies may be utilized, and Chekanov teaches that frequencies of 2-20Hz and 8-10Hz are more preferable (col. 2 lines 61-64). Thus, Hauck and Chekanov teach away from using frequencies below 2Hz. The Office Action states that col. 3 lines 60-64 teach the significant variability of therapeutic pulse requirements of different patients. However, the cited portions of Hauck apparently are concerned with field strength and not a timed spacing between fields (*see* col. 3 lines 58-66 of Hauck) as recited in the claims.

Regarding claim 15:

Applicant is unable to find, wherein one of the two leads is adaptable to be positioned in an anterior vein and a second of the two leads is adaptable to be positioned in a lateral vein, and the electrical field is a non-heart-excitatory signal passing through a left marginal artery and an anterior interventricular artery, as recited, among other things, in claim 15. The Office states that the positioning recited in the claim is inherently included in Hauck by a reference to electrodes implanted in coronary vessels (Hauck, col. 5 line 25). Applicant believes the cited portions are too vague to lead one of ordinary skill in the art to the positioning recited in claim 15. Applicant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, “In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art,” citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Therefore, because motivation is lacking to combine Chekanov with Hauck and because such a combination would not disclose all elements of all the contested claims, Applicant respectfully requests reconsideration and allowance of claims 1-20.

RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 09/852,919

Filing Date: May 10, 2001

Title: METHOD AND DEVICE FOR PREVENTING PLAQUE FORMATION IN CORONARY ARTERIES

Page 10

Dkt: 279.330US1

Applicant hereby incorporates all prior responses by reference to preserve all issues for appeal.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 349-9587 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

QINGSHENG ZHU ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

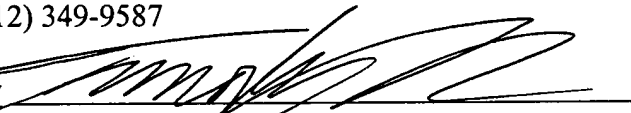
Minneapolis, MN 55402

(612) 349-9587

Date

16 May '05

By


Timothy B. Clise
Reg. No. 40,957

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 16 day of May, 2005.

Name

Paula Suchy

Signature

Paula Suchy